

TITLE 22. EXAMINING BOARDS
Part 15. Texas State Board of Pharmacy
Chapter 291. Pharmacies
Subchapter A. All Classes of Pharmacies

22 TAC §291.8

The Texas State Board of Pharmacy proposes repeal of §291.8 concerning Return of Prescription Drugs and simultaneously proposes new §291.8 concerning Return of Prescription Drugs. The new rule, if adopted, will implement the provisions of section 2.126, of H.B. 2292 passed by the 78th Legislative Session by establishing procedures: (1) for a consultant pharmacist in health care facilities to return unused drugs to pharmacies; and (2) for pharmacies to handle the returned drugs.

Gay Dodson, R.Ph., Executive Director/Secretary, has determined that, for the first five-year period the rule is in effect, there will be fiscal implications for state government as a result of enforcing or administering the rule. The Texas State Board of Pharmacy is unable to determine the actual amount of this fiscal impact since it will depend on rules yet to be adopted by the Health and Human Services Commission which establish the reimbursement rates for these returned drugs. There are no anticipated fiscal implications for local government.

Ms. Dodson has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the rule will be the establishing procedures for return unused drugs to pharmacies. There is no fiscal impact anticipated for small or large businesses or to other entities who are required to comply with this section.

A public hearing to receive comments on the proposed new rule will be held at 9:00 a.m. on Tuesday, November 18, 2003, at the Health Professions Council Board Room, 333 Guadalupe Street, Tower II, Room 2-225, Austin, Texas 78701. Persons planning to present comments to the Board are asked to provide a written copy of their comments prior to the hearing or bring 20 copies to the hearing. Written comments on the new rule may be submitted to Allison Benz, R.Ph., M.S., Director of Professional Services, 333 Guadalupe Street, Suite 3-600, Austin, Texas, 78701, FAX: 512/305-8082, E-mail: allison.benz@tsbp.state.tx.us. Comments must be received by 5 p.m., November 12, 2003.

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The repeal is proposed under sections 551.002 and 554.051(a) of the Texas Pharmacy Act (Chapters 551-566 and 568-569, Texas Occupations Code). The Board interprets section 551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets section 554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by this rule: Chapters 551-566 and 568-569, Texas Occupations Code.

291.8. Return of Prescription Drugs.

The agency hereby certifies that the proposed repeal has been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

22 TAC §291.8

The new rule is proposed under sections 551.002, and 554.051(a) of the Texas Pharmacy Act (Chapters 551-566 and 568-569, Texas Occupations Code) and section 2.126 of H.B. 2292 passed by the 78th Legislative Session. The Board interprets section 551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board

interprets section 554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act. The Board interprets section 2.126 of H.B. 2292 passed by the 78th Legislative Session as authorizing the agency to adopt rules to implement the provisions of the section.

The statutes affected by this rule: Chapters 551-566 and 568-569, Texas Occupations Code.

The agency hereby certifies that the proposed new rule has been reviewed by legal counsel and found to be a valid exercise of the agency's authority.

§291.8 Return of Prescription Drugs

(a) *General prohibition on return of prescription drugs.* As specified in §431.021(w), Health and Safety Code, a pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person, after the prescription or drug has been originally dispensed, or sold except as provided in subsection (b) of this section.

(b) *Return of prescription drugs from health care facilities.*

(1) *Purpose.* The purpose of this subsection is to outline procedures for the return of unused drugs from a health care facility to a dispensing pharmacy as specified in the Section 562.1085 of the Occupations Code. Nothing in this section shall require a consultant pharmacist, health care facility or pharmacy to participate in the return of unused drugs.

(2) *Definitions.* The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(A) *Consultant pharmacist* – A pharmacist who practices in or serves as a consultant for a health care facility in this state.

(B) *Health care facility* – A facility regulated under Chapter 142, 242, 247, or 252, Health and Safety Code.

(3) *Consultant pharmacist/health care facility responsibilities.* A consultant pharmacist may return to a pharmacy certain unused drugs, other than a controlled substance as defined by Chapter 481, Health and Safety Code, purchased from the pharmacy.

(A) The unused drugs must:

(i) be approved by the federal Food and Drug Administration and be:

(I) sealed in the manufacturer's original unopened tamper-evident packaging and either individually packaged or packaged in unit-dose packaging;

(II) oral or parenteral medication in sealed single-dose containers approved by the federal Food and Drug Administration;

(III) topical or inhalant drugs in sealed unit-of-use containers approved by the federal Food and Drug Administration; or

(IV) parenteral medications in sealed multiple-dose containers approved by the federal Food and Drug Administration from which doses have not been withdrawn; and

(ii) not be the subject of a mandatory recall by a state or federal agency or a voluntary recall by a drug seller or manufacturer.

(B) A healthcare facility may not return any drug product that:

(i) has been compounded;

(ii) appears on inspection to be adulterated;

(iii) requires refrigeration; or

(iv) has less than 120 days until the expiration date or end of the shelf life.

(C) The consultant pharmacist shall inventory the drugs returned to a pharmacy. The following information shall be included on this inventory:

(i) name and address of the facility or institution;

(ii) name and pharmacist license number of the consultant pharmacist;

(iii) date of return;

(iv) date the prescription was dispensed;

(v) unique identification number assigned to the prescription by the pharmacy;

(vi) name of dispensing pharmacy;

(vii) name, strength, and quantity of drug;

(viii) signature of consultant pharmacist;

(D) The pharmacist shall send a copy of the inventory specified in subparagraph (C)

of this paragraph to:

- (i) the pharmacy with the drugs returned; and
- (ii) the Health and Human Services Commission.

(4) *Dispensing/Receiving pharmacy responsibilities.* If a pharmacy accepts the return of unused drugs from a health care facility, the following is applicable.

(A) A pharmacist employed by the pharmacy shall examine the drugs to ensure the integrity of the drug product.

(B) The pharmacy shall reimburse or credit the entity that paid for the drug including the state Medicaid program for an unused drug returned to the pharmacy. The pharmacy shall maintain a record of the credit or reimbursement containing the following information:

- (i) name and address of the facility or institution which returned the drugs;
- (ii) date and amount of the credit or reimbursement was issued;
- (iii) name of the person or entity to whom the credit or reimbursement was

issued;

- (iv) date the prescription was dispensed;
- (v) unique identification number assigned to the prescription by the

pharmacy;

- (vi) name, strength, and quantity of drug;
- (vii) signature of the pharmacist responsible for issuing the credit.

(C) After the pharmacy has issued credit or reimbursement, the pharmacy may restock and redispense the unused drugs returned under this section.

(5) *Limitation on Liability.*

(A) A pharmacy that returns unused drugs and a manufacturer that accepts the unused drugs under Section 562.1085, Occupations Code, and the employees of the pharmacy or manufacturer are not liable for harm caused by the accepting, dispensing, or administering of drugs returned in strict compliance with Section 562.1085, Occupations Code, unless the harm is caused by:

- (i) wilful or wanton acts of negligence;
- (ii) conscious indifference or reckless disregard for the safety of others; or
- (iii) intentional conduct.

(B) This section does not limit, or in any way affect or diminish, the liability of a drug seller or manufacturer under Chapter 82, Civil Practice and Remedies Code.

(C) This section does not apply if harm results from the failure to fully and completely comply with the requirements of Section 562.1085, Occupations Code.

(D) This section does not apply to a pharmacy or manufacturer that fails to comply with the insurance provisions of Chapter 84, Civil Practice and Remedies Code.